

NEIFELD Docket No.: EDWA0018U-US

IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF: White et al.

GROUP ART UNIT: 3731

SERIAL NO.: 10/733,292

CONFIRMATION NO.: 2518

EXAMINER: Michael Thaler

FILED: 12/12/2003

FOR: Intraluminal Graft

Neifeld Docket No: EDWA0018U-US

Application/Patent No: 10/733,292

USPTO CONFIRMATION NO: 2518

File/Issue Date: 12/12/2003

Inventor/title: White et al./Intraluminal Graft

Examiner/ArtUnit: Michael Thaler/3731

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37 CFR 41.50(B)(2) REQUEST FOR REHEARING

Sir:

Pursuant to 37 CFR 41.50(b)(2), the appellant requests rehearing.

INTRODUCTION

The decision misapprehended the law and overlooked the facts as noted below. The panel's new rejections are improper and should be reversed or withdrawn, as the case may be.

The panel's exercise of jurisdiction to identify additional material facts and make additional conclusions of law not presented by the examiner was inadvisable. At most, the panel should have considered remanding for the examiner to review the facts and law. That option still exists if the panel is not entirely convinced by the discussion below that its newly imposed rejections are improper.

DECISION ON APPEAL AND NEW GROUNDS OF REJECTION

The decision on appeal reversed all grounds of rejection.

The decision on appeal also entered new grounds of rejection under 37 CFR 41.50(b). 37 CFR 41.50(b) reads as follows:

(b) Should the Board have knowledge of any grounds not involved in the appeal for rejecting any pending claim, it may include in its opinion a statement to that effect with its reasons for so holding, which statement constitutes a new ground of rejection of the claim. A new ground of rejection pursuant to this paragraph shall not be considered final for judicial review. When the Board makes a new ground of rejection, the appellant, within two months from the date of the decision, must exercise one of the following two options with respect to the new ground of rejection to avoid termination of the appeal as to the rejected claims:

(1) Reopen prosecution. Submit an appropriate amendment of the claims so rejected or new evidence relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the proceeding will be remanded to the examiner. The new ground of rejection is binding upon the examiner unless an amendment or new evidence not previously of record is made which, in the opinion of the examiner, overcomes the new ground of rejection stated in the decision. Should the examiner reject the claims, appellant may again appeal to the Board pursuant to this subpart.

(2) Request rehearing. Request that the proceeding be reheard under § 41.52 by the Board upon the same record. The request for rehearing must address any new ground of rejection and state with particularity the points believed to have been misapprehended or overlooked in entering the new ground of rejection

and also state all other grounds upon which rehearing is sought.

REQUEST FOR REHEARING

The appellant requests rehearing under 37 CFR 41.40(b)(2), and addresses herein below the points misapprehended and overlooked in the new grounds of rejection, with reference to claim 12. Claim 12 reads as follows:

12. A prosthesis for placement in a lumen of the first vessel that intersects with a second vessel, the prosthesis comprising:

a first end,

a second end, and

wherein at least one of the first and second ends is provided with a wire structure which has a plurality of apices extending beyond at least a portion of the corresponding end such that the plurality of apices extend across a lumen of the second vessel without occluding the lumen of the second vessel.

NEW GROUNDS FOR REJECTION

The new grounds of rejection read as follows.

5. ANTICIPATION BY PIPLANI

Under the provisions of 37 CFR 8 41.50(b), we enter the following new ground of rejection: claims 12- 16, 19,20,22, and 24-36 are rejected under 35 U.S.C. 5 102(e) as anticipated by Piplani. Piplani describes a tubular bifurcated intraluminal graft prosthesis, having first and second ends (Piplani, Figure 4). The device can be placed in the lumen of a first vessel that intersects a second vessel (see *id.* at Figures 13 through 19). The device's main body can be from five to thirty centimeters long, with a diameter of from twelve to thirty millimeters (*id.* at col. 5, 11. 16-22).

Piplani's device comprises an expandable spring attachment means 126, having a generally sinusoidal or zig-zag shape, with a plurality of wire apices 132 that extend from the body of the graft (*id.* at Figure 4; col. 5, ll. 29-58.) The spring attachment must be physically expanded "from an initial compressed or collapsed position to a subsequent expanded position" to allow it to press against the inner surface of a vessel (*id.* at col. 5, ll. 39-40).

Piplani's device also has first and second wires not at the end of the prosthesis (*id.* at col. 5'11. 23-27).

Regarding the limitation in claims 12 and 20 requiring the device's wire apices to be capable of extending across an intersecting vessel, Piplani discloses that

the apices 132 lie in three longitudinally spaced-apart parallel planes extending transversely of the axis of the expandable spring attachment means in which the first plane is disposed internally of the open end and the second plane lies in a position which is external of but in close proximity to *the open end and the third plane is spaced a substantial distance beyond the open end.*

(Id. at col. 5, ll. 51-58, emphasis added.) Thus, Piplani's graft has two sets of wire apices that extend beyond the body of the graft. One set of apices is "in close proximity" to the open end of the graft, while the other set of apices is "a substantial distance" from the end of the graft (id. at col. 5, ll. 55-58).

In view of the drawings, the explicitly stated dimensions, and the disclosure that one set of wire apices extends "a substantial distance" from the body of the graft, it is reasonable to conclude that the wire apices of Piplani's device would extend a sufficient distance from the body of the graft such that the apices would be capable of extending across the lumen of an intersecting vessel, including a renal artery. Therefore, Piplani's device reasonably appears to meet the structural limitations of claims 12- 16, 19,20.

As stated in In re Best, 562 F.2d 1252, 1254-55, 195 USPQ 430,433 (CCPA 1977):

Where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on.

In reviewing Appellants' arguments, we do not find any evidence demonstrating that this conclusion is not reasonable. On the current record,

Appellants have not met their burden under In re Best of establishing a difference between the claims and prior art.

In response, the appellant submits that the panel has misapprehended both law and fact. First, the panel has misapprehended the law of inherency. the panel relies upon Piplani's disclosure of "*a substantial distance*" in Piplani's statement that "*the third plane is spaced a substantial distance beyond the open end*" to conclude that Piplani's apices necessarily extend from Piplani's graft a distance sufficient to "extend across a lumen of the second vessel without occluding the lumen of the second vessel" as defined by claim 12. However, "substantial" is a relative term. Piplani provides no metric to specify what "substantial" means. Hence, the panel has not demonstrated that claim 12's limitation is inherent in Piplani. That is, the panel, like the examiner, has not shown that Piplani's apices necessarily are long enough to extend across a renal artery.

The panel's reliance upon Best is improper; reliance upon Best is both out of context of the facts of Best and inapplicable to the facts of this case. Best relates to products formed by a process wherein the novel property ascribed to the claimed product results from alleged differences in the process of its manufacture, compared to the prior art. In Best, the allegedly novel process step was a rate of cooling. ("Our reading of Hansford leads us to conclude, as did the board, that all process limitations of claim 3 are expressly disclosed by Hansford, except for the functionally expressed rate of cooling. Because any sample of Hansford's calcined zeolitic catalyst would necessarily be cooled to facilitate subsequent handling, the conclusion of the examiner that such cooling is encompassed by the terms of the appealed claims was reasonable.") The CCPA affirmed the Board in Best because there was no showing by appellant that a different rate of cooling resulted in the allegedly novel property of the claimed product over the prior art product. In contrast, Piplani discloses an apparatus. There is nothing in Piplani susceptible to testing and presentation of comparative data; no process of chemical manufacturing. Unlike in Best. No allegedly novel feature of a composition of matter based upon a process of making a composition is involved in this case. Unlike in Best. Hence, Best is not applicable.

In fact, all Best says is that the USPTO can "require the applicant to prove that the subject matter shown to be in the prior art does not possess the characteristic relied on." The applicants have made such a showing viz Piplani in their appeal brief, pointing out that Piplani did not expressly or inherently disclose. The Board agreed by reversing the examiner's inherency rejections based upon Piplani. The prior art in this case is Piplani, and Piplani does not expressly

or inherently disclose apices that "extend across a lumen of the second vessel without occluding the lumen of the second vessel" as defined by claim 12. The panel was led astray by the word "substantial". However, all "substantial" means is not insubstantial. It does not for example mean at least 1, 3, 5, or 15 millimeters. Therefore, the panel should reconsider and withdraw or reverse, as the case may be, its new grounds for rejection.

Furthermore, the panel's reliance upon its own quotation of Piplani col. 5, ll. 51-58 is misplaced because that quotation is only part of sentence, and it mischaracterizes the facts because the omitted portion of the sentence is relevant. Here, the panel made an error in fact. The panel quoted a portion of a sentence from Piplani, omitting the important qualifying clause in that sentence: "As disclosed in the co-pending application Ser. No. 07/553,350 filed Jul. 13, 1990". The full sentence from Piplani reads:

As disclosed in the co-pending application Ser. No. 07/553,350 filed Jul. 13, 1990, the apices 132 lie in three longitudinally spaced-apart parallel planes extending transversely of the axis of the expandable spring attachment means in which the first plane is disposed internally of the open end and the second plane lies in a position which is external of but in close proximity to the open end and the third plane is spaced a substantial distance beyond the open end. [Italics added for emphasis.]

The panel decision relied *only* upon the non italicized portion of the foregoing sentence to conclude that "a substantial distance" meant that Piplani anticipated claim 12's "apices *extend across* a lumen of the second vessel without occluding the lumen of the second vessel." The panel ignored the reference in the very same sentence to what Piplani indicated he meant by "a substantial distance". The phrase "*As disclosed in*" means that the following words in the same sentence were to be interpreted in view of what was "*disclosed in ... co-pending application Ser. No. 07/553,350 filed Jul. 13, 1990.*" The panel overlooked that fact. Moreover, Piplani's reference to "co-pending application Ser. No. 07/553,350 filed Jul. 13, 1990" is as a matter of law an incorporation by reference of co-pending application Ser. No. 07/553,350 filed Jul. 13, 1990. Incorporation by reference requires a specific identification of another document, and language indicating an intent to incorporate, both of which are present in Piplani's "As disclosed in ..." sentence. Therefore, Piplani incorporated by reference what was disclosed in co-pending application Ser. No. 07/553,350 filed Jul. 13, 1990, at least to the extent of clarifying the

structure of the apices, the spring attachment means, and the corresponding open end of the graft. Thus, the panel overlooked facts very relevant to its conclusion. Therefore, the panel should withdraw or reverse its rejections based upon its conclusion that Piplani anticipates claim 12, because they are based upon an inaccurate interpretation of what Piplani meant by "substantial". Inaccurate, in the sense of being inconsistent with Piplani's entire disclosure. At a minimum, the panel should remand to the examiner for the examiner to consider whether what is disclosed in co-pending application Ser. No. 07/553,350 filed Jul. 13, 1990 supports a rejection.

A review of the incorporated by reference document indicates that Piplani did not disclose a structure having apices that are long enough to "extend across a lumen of the second vessel without occluding the lumen of the second vessel," as defined by claim 12.

Piplani's reference to 07/553,350 is however clearly erroneous and the correct reference is readily identifiable. Application Ser. No. 07/553,350 filed Jul. 13, 1990, issued as USP 5,038,681. USP 5,038,681 disclosed unrelated subject matter. See its title "Control method and apparatus for spray dampener". It discloses no apices.

USP 5,275,622 to Lazarus was co-pending with Piplani, refers to apices and endovascular grafts, and it issued from application 07/553,530. Note that 07/553,530 is identical to the referenced application in Piplani (07/553,350) but for transposition of a 3 and a 5. In addition, Piplani and Lazarus have a common inventor, Wesley Serman. In addition, Lazarus also refers to the planes 141, 142, 143 for locating apices of the spring attachment means. Accordingly, evidence shows to a certainty that Piplani intended to refer to USP 5,275,622 to Lazarus. Since Piplani's citation error is clear, and since the intended application is unambiguously and uniquely identifiable, the incorporation by reference is legally effective.

Lazarus is directed to Endovascular grafts. Title. The portions of Lazarus relevant to the apices limitation of claim 12 are Figs. 10 and 11; col. 2 lines 24-26; col. 2 lines 54-61; col. 8 line 25 to col. 10 line 21; col. 11 lines 40-49; and col. 12 lines 11-14.

Figs. 10 and 11 show the graft and spring/hook structure respectively.

Col. 2 lines 24-26 are the brief descriptions of Figs 10 and 11, indicating that they show a view of the graft (Fig. 10) and an enlarged view of the "spring attachment means utilized on the graft" (Fig. 11).

Col. 2 lines 54-61 is the portion of the summary of the invention dealing with the graft which states in part that "hook like attachment means is secured to the proximal and distal ends" of the tubular graft.

Col. 8 line 25 to col. 10 line 21 are the detailed description of the grafts and spring/hook

structure shown in Figs. 10-11. This passage includes discussion of the three parallel planes 141, 142, and 143, and the apices lying in those planes, and design criteria indicating that planes 141, 142, 143 should be closely spaced to retain sufficient spring force, as discussed below. It states in part that the following passages.

First:

The spring means 131 is secured to the first and second ends 123 and 124 of the tubular member by suitable means such as a Dacron polyester suture material 146 which is utilized for sewing the spring means onto the tubular member. This can be accomplished by a sewing operation with the suture material 146 extending into and out of the wall 126 of the tubular member and in which knots 147 are formed on each of the legs or struts 137 and 138 in such a manner so that the apices lying in the plane 141 extend outwardly and are spaced from the end on which they are mounted and in which the apices lying in the plane 142 extend just beyond the outer edge of the tubular member and in which the apices in the third plane are positioned inwardly from the outer edge. [Col. 9 lines 3-12.]

This passage indicates that plane 141 is spaced from the end, and that plane 142 is "just beyond" the end of the tube. What this passage connotes is that the apice at plane 142 is as close to the end as possible. It does not connote that plane 141 is spaces great distances from the end, only that it is further from the end than plane 142.

Second:

It has been found that the spring force created by the helical coils 136 at the apices 133 is largely determined by the diameter of the wire. The greater the diameter of the wire, the greater the spring force applied to the struts or legs 137 and 138 of the vees. *Also, the longer the distances are between the apices lying in planes 141 and 142, the smaller the spring force that is applied to the legs or struts 137 and 138.* It therefore has been desirable to provide a spacing between the outer extremities of the legs or struts of approximately one centimeter, although smaller or larger distances may be utilized. [Col. 9 lines 35-46' italics added for emphasis.]

This passage is discussing how to provide sufficient spring force to spring open the graft and force the hooks into the walls of the vessel. Thus, the italicized text indicates positively that *the longitudinal distances between the apices should be minimized*. What this means is that Lazarus teaches, and hence Piplani teaches, that the apices are in actual design close to one another relative to the other dimensions of the graft. Hence, this passage in Lazarus contradicts the panel's conclusion upon which the new grounds of rejection are based.

Third:

The helical coil springs 136 placed at the nodes or apices 133 of the vees 132 of the spring means 131 serve to facilitate compression of the graft when it is desired to place the same within the capsule 36 as hereinafter described. The compression of the graft is accomplished by deformation of the coil springs 136 within their elastic limits. *Placing the nodes or apices 133 in different planes greatly aids in reducing the size to which the graft can be reduced during compression of the same by staggering or offsetting the hooks or hook-like elements 151. This also helps to prevent the hook-like elements from becoming entangled with each other.* The natural spring forces of the helical coil springs 136 provided in the apices of the vees serves to expand the graft to its expanded position as soon as the graft is free of the capsule 36. By way of example, as shown in the drawings, three apices or nodes can be provided in the plane 141 and three apices or nodes in the plane 142 which are offset longitudinally with respect to the nodes in plane 141 and six nodes in plane 143. The placement of six nodes or apices 133 in the plane 143 does not interfere with the compression of the graft 151 because there are no hook-like elements 151 at these nodes or apices 133 in the plane. For larger diameter grafts, the spring means 131 can be provided with additional apices or nodes 133 to enhance attachment as hereinafter described. [Col. 9 line 63 to column 10 line 21; italics added for emphasis.]

The foregoing passage explains the reason why the apices are in staggered planes 141, 142, 143. It explains that staggering allows additional compression of the graft by avoiding the hooks from becoming entangled in each other. Thus, Lazarus teaches two design constraints on the location of the apices. First, the apices having hooks need to be staggered to allow compression of the graft for insertion in the catheter; there need to be no hooks overlapping in

the same longitudinal position. Second, the staggering should be minimized to provide for the greatest spring force. From those two constraints, Lazarus teaches that the planes 141, 142, 143 should be staggered in the longitudinal direction by an amount slightly greater than the extent of each hook in the longitudinal direction. Lazarus provides absolute dimension for its hooks, and their cant from the transverse direction, in the following two passages.

Hook-like elements 151 are provided on the apices lying in planes 141 and 142 and are secured to the vees 132 in the vicinity of the apices by suitable means such as welding. The hook-like elements 151 can have a suitable diameter such as 0.010 to 0.14 inches and *a length from 0.5 to 3 millimeters*. The hook-like elements are sharpened to provide conical tips. The hook-like elements 151 should have a length which is sufficient for the hook to penetrate into the vessel wall, but not through the vessel wall. [Col. 9 lines 13-22; italics added for emphasis.]

The hook-like elements 151 at the proximal and distal extremities of the graft 121 are angled at suitable angles with respect to longitudinal axis of the tubular member 122. The hook-like elements face towards each other to facilitate holding the graft 121 in place in the vessel of the patient. *Thus, the hook-like elements 151 on the proximal extremity 123 are inclined from the longitudinal axis by 55.degree. to 80.degree. and preferably about 65.degree. toward the distal end of the graft 121 in the direction of blood flow. The hook-like elements 151 on the distal end 124 of the graft or implant 121 are inclined from the longitudinal axis by 30.degree. to 90.degree. and preferably 85.degree. in a direction towards the proximal end 123 and opposite the direction of blood flow.* The hook-like elements 151 serve as attachment means at each end of the graft 121 and when implanted oppose migration of the graft. [Col. 9 lines 47-63; italics supplied for emphasis.]

The foregoing two passages show that the longitudinal extent of each hook is no more than about 1-2 millimeters. Hence, Lazarus teaches that spacing between apices (at which the

hooks are connected) should be no more than about 1-2 millimeters. It is also reasonable to assume from Lazarus, since Lazarus addresses sizing of grafts to patients, that the largest hooks would correspond to grafts for patients with the largest arteries; both aortic and renal.

In any case, a spacing of 1-2 millimeters for Piplani's apices would not result in Piplani having an apice that meets the limitation of claim 12 that the "apices extend across a lumen of the second vessel." The applied prior art does not specify the dimension of the renal artery to be less than 2 millimeters. Therefore, the new grounds of rejections are improper because they are not based upon apices having a longitudinal spacing of not more than 2 millimeters.

Moreover, the dimensions of the openings of the renal artery and the ratio of that dimension to the diameter of the aortic artery are presumably well known. The new grounds of rejection improperly shift the burden under the theory that the applicant is in the best position to determine facts not available to the Office, such as comparative data. However, the general rationale for burden shifting is inapplicable in this case, because in this case, whatever information exists regarding dimensions of the aortic and renal arteries, is equally available to the Office and the applicant.

Given that this case is under appeal and appellant cannot submit new evidence, the new grounds of rejection is untenable. The panel should reverse its new grounds of rejection because Best is inapplicable, and because the factual basis for the rationale underlying the panel's rejection is incomplete, lacking evidence of the diameter and ratios of the aortic and renal arteries. At most, the panel should remand for the examiner or the applicant to make suitable factual findings on the record.

Respectfully Submitted,

6/26/2007

DATE

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Printed: June 26, 2007 (7:13pm)

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